UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,931	08/27/2003	Jong-Soo Woo	DE-1500	8064

1109 7590 03/15/2007

ANDERSON, KILL & OLICK, P.C.
1251 AVENUE OF THE AMERICAS
NEW YORK,, NY 10020-1182

EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/650,931	WOO ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Response filed February 7, 2007 to the Election Requirements is acknowledged. New claim 10 is presented.

Along with original claims 1-9, claims 1-10 are now under consideration wherein the subject matter presently under consideration are those sustained-release compositions for oral administration comprising the drug nifedipine, a mixture of sodium alginate and xanthan gum, representing the carrier for sustained release of nifedipine and a mixture of hydroxypropyl methylcellulose and propylene glycol alginate, representing the gel hydration accelerator.

Those compositions comprising other drugs, carriers and gel hydration accelerators are presently withdrawn from consideration by the Examiner as drawn to non-elected inventions. Re-affirmation of the elections is requested when Applicants respond to this Office Action.

An Information Disclosure Statement filed November 8, 2004 is further acknowledged. PTO Form-1449 is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal, A.R., WO 97/39050, in view of Moroni et al., U.S. Patent 6,465,014, and Mulye et al., U.S. Patent 6,416,786.

Baichwal teaches sustained-release compositions comprising nifedipine for oral administration. See page 15. The inclusion of at least one gelling agent such as an alginate and a cellulose such as hydroxypropylmethylcellulose are also required. See claims 7 and 8 on page 45. In a preferred embodiment xanthan gum is required as a gelling agent. As required by instant claim 5, locust bean gum is included in the carrier of the sustained-release oral dosage forms. See, *inter alia*, page 5, lines 17-19. Although moistening agents such as water, polyethylene glycol, glycerol and alcohol are recited, propylene glycol alginate is not. However, as taught by Moroni and Mulye, sodium alginate, propylene glycol alginate, sodium alginate and xanthan gum are known in the prior art for their utility in sustained-release formulations of a pharmaceutical medicament. See column 5, lines 37-44, in U.S. Patent 6,416,786, where both sodium alginate and xanthan gum are specifically disclosed as essential ingredients of the carrier. Mulye further teaches the inclusion of hydrophilic polymers such as hydroxypropylmethylcellulose. See column 4, lines 40-41. Moroni teaches the requirement of sodium alginate and propylene glycol alginate in sustained-release drug delivery compositions. See claim 1, column 4. The open language of the present claims allows for the inclusion of any number of additional active or inactive agents.

With respect to claimed weight ratios as recited in instant claims 3, 4, 6 and 7, it is not inventive to discover the optimum or workable ranges by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(II). The determination of the optimum ratio to employ with the presently claimed active and

inactive agents would have been a matter well within the purview of one of ordinary skill in the art. Such determination would have been made in accordance with a variety of factors. These would have included such factors as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered a part of a drug combination. Thus, in the absence of evidence to the contrary, the currently claimed specific proportions of the claimed ingredients are not seen to be inconsistent with the ratios that would have been determined by the skilled artisan in formulation chemistry.

No claim is allowed.

Zhang et al., U.S. Patent 6,264,981, is cited to show further the state of the art.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

March 12, 2007 Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER